Memorandum

U.S. Department
of Transportation
**Federal Aviation
Administration**

Subject: **Action:** Automatic External Defibrillator (AED) Operating Guidance

Date: December 11, 2000

From: Federal Air Surgeon, AAM - 1

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To: Director, Civil Aeromedical Institute, (CAMI)
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General:

The following guidance is to be followed by Office of Aviation Medicine (AAM) personnel in the implementation and operation of automatic external defibrillators (AED) in Federal Aviation Administration (FAA) facilities. Overall responsibility for this initiative is assigned to AAM-200; however, regional flight surgeons (RFS) shall be responsible for the specific implementation of the provisions of this initiative in their geographic areas of responsibility.

Implementation of AED usage requires at least six activities:

1. Evaluation to determine appropriate placement of the resuscitation equipment.
2. A plan for implementing personnel training and retraining.
3. Medical oversight by physicians trained in use of the equipment and in cardiopulmonary resuscitation.
4. To assure effectiveness and quality control, management of information collected on AED placement; and provider, trainer certification and currency.
5. Data collection protocols to ascertain personnel and equipment performance.
6. A mechanism to follow-up patient outcomes following the use of an AED.

This operating guidance is designed to address these and other issues. The appendices contain additional guidance and forms to achieve these activities.

Background:

AED's are safe and accurate medical devices used to deliver an electrical shock to persons in cardiac arrest. The new, portable AED's enable anyone trained in their use to respond to a cardiac arrest emergency that requires defibrillation. The AED's must be employed within a system that includes cardiopulmonary resuscitation (CPR) and the activation of the Emergency Medical System (EMS or "911") which

together form a chain of survival. AED's are an important component of this chain because they can restore normal heart rhythm in victims of sudden cardiac arrest; however, trained individuals must use them on the victim within a matter of minutes. When a person suffers a sudden cardiac arrest, their chance for survival decreases by 7% to 10% for each minute that passes without defibrillation.

Scope:

The Office of Aviation Medicine has purchased a limited number of AED's for deployment in major FAA facilities with a medical unit where medical employees have received the requisite training for use of the devices and training in cardiopulmonary resuscitation. However, the successful full deployment and usefulness of AED's in facilities outside medical units or where medical units do not exist depends upon non-AAM employees willing to participate in training and act as first responders in an actual medical emergency involving a cardiac arrest. A cadre of trained responders must be created prior to deployment of an AED outside a medical unit. Through voluntary participation of non-medical employees and through providing the requisite training, lines of business (LOB) may elect to provide AED's and create small groups of employees to act as first responders. Such action on the part of LOB's would permit deployment of AED's outside medical units but still under AAM management, control, and responsibility. As a trained responder, a FAA employee is acting on behalf of the agency and to that purpose, the employee who participates and complies with guideline requirements will be considered to be acting within the scope of his or her employment.

Goals and Objectives:

This guidance provides medical direction and mechanisms for quality assurance so that in the event an AED responder is called upon to resuscitate/defibrillate a cardiac arrest victim, the procedures and protocols employed will optimize the chance of survival.

AED's are classified as medical devices by the Food and Drug Administration (FDA) in accordance with 21 CFR 801.109. Federal law restricts this device for sale to or on the order of a physician. Medical oversight is therefore, a requirement. Medical oversight includes the development of guidelines consistent with current standards of care, training and certification of responders, and post-resuscitation event review by a physician.

Responsibilities:

1. Manager, Medical Specialties Division. The Manager, Medical Specialties Division (AAM-200) is responsible for the general oversight and direction for the deployment and use of AED's in FAA facilities. These responsibilities include, but are not limited to:
    (a) Establishment of protocols for first responder care.
    (b) Development of mechanisms to monitor quality in all aspects of the program.
    (c) Development of national training guidelines for agency personnel in AED use and CPR.

(d) Development of national protocols to track quality of services, equipment maintenance, and patient outcomes.
(e) Development of a national process for reporting and debriefing personnel on every episode of use of a FAA AED.

2. Regional Flight Surgeons. Regional Flight Surgeons are responsible for ensuring that the directives of AAM-200 are implemented and complied with. They will as a minimum:
   (a) In coordination with the appropriate LOB, determine the placement of the AED's in their respective areas of responsibility.
   (b) In coordination with appropriate LOB's insure deployment of the equipment in accordance with established guidelines.
   (c) Establish procedures to account for maintenance, battery replacement, damage or loss of AED equipment.
   (d) Establish a local process to track patient outcomes with every procedure.
   (e) In coordination with the appropriate LOB, develop a process to ensure currency of training of first responders (initial and recurrent), including bloodborne pathogens awareness, at all facilities with AED's within their regions. Similarly, account for currency of training of any FAA trainer in their region.
   (f) Develop methods to track and report every AED use and patient outcomes to AAM-200.

3. AED Site Coordinator. To achieve AED deployment outside medical units, LOB's must identify an AED site coordinator. The AED Site Coordinator is an employee of the FAA who is the primary liaison between the LOB and the RFS. This person will have the responsibility for maintaining all the facility's AED/CPR equipment and supplies, organizing initial and recurrency training programs for responders, creating and forwarding an incident data form to the RFS and holding post-incident debriefing sessions with the RFS and responder. LOB's will be responsible for cost of replacement of equipment and supplies.

4. CPR/AED First Responders or Providers. Agency personnel with current certification in CPR/AED may be given the Hepatitis-B vaccination (HBV). It is highly recommended but voluntary. Recurrent training and certification every two years is an on-going requirement for providers in this program, except training by the American Red Cross (ARC) must be renewed annually.

5. CPR/AED Trainers.
   (a) FAA Personnel: Selected FAA physicians, nurses, or other qualified agency personnel certified by nationally recognized associations such as the American Heart Association (AHA), the American Red Cross, or the National Safety Council (NSC) will provide training to selected agency employees. Training shall be conducted in accordance with nationally recognized curricula and protocols pre-approved by AAM-200.

   (b) Non-FAA Personnel: Certified trainers credentialed by nationally recognized associations such as the American Heart Association (AHA), the American Red Cross (ARC), or the National Safety Council (NSC) may

provide the CPR/AED training and certification for selected agency employees under applicable regulations/guidance.

Key Guideline Elements:

Prior to implementation of these guidelines the following minimum elements shall be in place:

(a) AED Treatment Algorithm*
(b) Quality Assurance Plan*
(c) Employee Education, Training and Certification*

(* See appendices)

Agency Coordination and Cooperation:

Through AAM-200 and RFS's AAM will establish and internal process to ensure coordination and cooperation with LOB's regarding deployment and usage of AED's. AAM anticipates both national and regional partnerships with the LOB's and bargaining units for this purpose. The LOB's and bargaining units are encouraged to educate their members about this initiative and actively recruit and designate volunteers to participate as first responders.

Jon L. Jordan, M.D.

Attachments
Appendix A - Indemnification
Appendix B - Emergency Response Plan
Appendix C - AED Treatment Algorithm
Appendix D - Quality Assurance Plan
Appendix E - Maintenance Guidelines
Appendix F - Database AED Tracking
Appendix G - AED and FAA Equipment Compatibility Report
Appendix H - AED Incident Review

APPENDIX A

INDEMNIFICATION

Heartstream, Inc. shall defend, indemnify, hold harmless, and at its option settle, any claims or actions for injury or damages to persons or tangible property brought against any person or entity who purchases, rents or leases a ForeRunner® Automatic External Defibrillator ("ForeRunner") from Heartstream, Inc., or one of its authorized distributors if:

(1) such claim or action arises from the mechanical or electrical failure or malfunction of the ForeRunner; and

(2) such claim or action did not result from the negligence, gross negligence or improper acts of any person or entity not employed by or under the control of Heartstream, Inc.

This indemnification does not extend to or cover any claims involving: a ForeRunner not kept in proper working order; the use of non-Heartstream or out-of-date pads or battery; the operation of a ForeRunner by a person not authorized or trained to use it; not operating the ForeRunner under medical direction or supervision; or the failure to follow the operating instructions.

This indemnification is expressly contingent on the person or entity promptly providing Heartstream with: notice of any such claim or action after obtaining actual knowledge thereof; accurate and complete assistance and information (including the data card containing the record of the event which is the subject of the claim) giving rise to the claim or action; and the unrestricted authority to defend or settle such claim or action, provided, however, that the person or entity seeking indemnification shall have the right to participate at their own expense in any such defense or settlement.

APPENDIX B
Emergency Response Plan

EMERGENCY RESPONSE PROTOCOL

IN CASE OF EMERGENCY, INITIATE CHAIN OF SURVIVAL

EARLY ACCESS	EARLY CPR	EARLY DEFIBRILLATION	EARLY ADVANCED CARE

Early CPR

1. Assess scene safety.

2. Assess responsiveness. Tap shoulder and shout "Are you OK?"

3. Activate emergency response plan.

4. Call _____ (e.g., receptionist), who will:

5. Call 9-1-1. Provide dispatcher with location, emergency details and notify them that an AED is being deployed within the company.

6. Broadcast over the PA system an announcement to activate targeted responders and indicate the location of the patient (e.g., CODE BLUE, building 2, cafeteria).

7. Call designated person (with pass for all security clearance locations) to wait at the front entry and help lead the EMS personnel to the victim.

8. Check ABCs:
   (a) Assess Airway. Perform head-tilt, chin lift to open airway.
   (b) Assess Breathing. Look, listen, feel. If breathing is absent, use barrier mask to deliver 2 rescue breaths.
   (c) Assess Circulation. Check carotid pulse. If pulse is absent begin CPR.

9. Early CPR

10. Perform CPR until the ForeRunner arrives:

11. Compress and release chest 15 times (Rate 80-100 compression/minute).

12. Ventilate. Give 2 rescue breaths.

13. Continue CPR. 15 compressions/2 rescue breaths.
    Check pulse after 4 cycles and every few minutes there after.

Early Defibrillation

Instructions for rescuer approach:

1. When defibrillator arrives:
    (a) Place ForeRunner near head patient on same side as the rescuer.
    (b) Turn on the ForeRunner.
    (c) Bare and prepare chest (cut or tear away clothing, if excessive chest hair, shave or clip; dry the chest if wet).

2. Follow ForeRunner's verbal and visual prompts
    (a) Apply electrodes (follow drawings on pad).
    (b) Allow ForeRunner to analyze.
    (c) If indicated, deliver shock by pressing the orange button.

3. Continue care per ForeRunner AED Treatment algorithm (Appendix C).

Early Advanced Care Life Support

1. Have a designated person wait for EMS providers at front entry of main building and help guide them through building and security doors to the patient.

2. Responders working on the victim should communicate any important information to the EMS providers such as:

    (a) Victim's name.
    (b) Any known medical problems, allergies or medical history.
    (c) Time the victim was found.
    (d) Initial and current condition of victim.
    (e) Information from ForeRunner screen: Number of shocks delivered; length of time defibrillator has been used.

3. Help EMS personnel as requested.

APPENDIX C
AED TREATMENT ALGORITHM

Automated External Defibrillation (AED) Treatment Algorithm

Immediately Upon Arrival, Verify Sudden Cardiac Arrest (SCA)

1. Verify unconsciousness - Assess responsiveness – is the individual responsive
2. Activate the emergency response plan – **notify management**
3. Open airway
4. Verify no breathing
5. Deliver 2 rescue breaths
6. Verify no carotid pulse

After Verification of SCA

1. Perform CPR if there is a delay in obtaining or using the ForeRunner
2. Turn on the ForeRunner
3. Follow verbal and visual prompts
4. Apply defibrillation pads

Allow ForeRunner to Analyze (Automatic)

"Shock Advised"

1. Clear patient verbally and visually prior to shock delivery
2. Deliver shock
3. Defibrillate up to three times
4. Check pulse
   (a) If absent, perform CPR for one minute*

* Continue sequence of three shocks and one minute of CPR until "no shock" prompt or EMS arrives.

"No Shock Advised"

1. Check Pulse
   (a) If absent, perform CPR
   (b) If present, support airway and breathing - Continue until ForeRunner prompts, "Do not touch the patient" or EMS arrives.

Note: Adapted from American Heart Association (AHA) AED Treatment Algorithm 10/97.

APPENDIX D
QUALITY ASSURANCE PLAN

Responder Post-use Checklist

The AED Coordinator will do the following after any AED use:

1. Notify Regional Flight Surgeon (RFS) or the Occupational Health physician at the Aeronautical Center
2. Remove used PC data card and replace it with a spare. Label used PC data card with patient information and deliver to appropriate personnel according to medical protocol or local guidelines.
3. Conduct employee incident debriefing, as needed.
4. Complete incident follow-up report deemed necessary by Medical Director
5. Restock any used electrode pads, batteries, razors or gloves
   Inspect unused supplies for any damage or old expiration dates.
6. Remove and replace battery in the ForeRunner and do a Battery Insertion Test (BIT) prior to replacing ForeRunner into service.
7. Clean the ForeRunner.
8. Review User's Guide for list of appropriate cleaning agents.

Regular Maintenance

See Appendix E or ForeRunner User's Guide

Daily and After Each Use

1. Verify alternating dark and hourglass shapes indicating readiness for use.
   See Appendix E or ForeRunner User's Guide

2. Ensure all supplies and spares are present and are in report as deemed necessary by operating condition. Check expiration dates and any obvious signs of damage.

3. Inspect the exterior and connector for signs of damage.

3. Check status indicator.

4. Perform a Battery Insertion Test (BIT) to confirm ForeRunner is ready to be put back in service.

5. Remove PC data card and replace it with a spare. Apply a patient ID label to the used PC data card and deliver to the appropriate personnel.

AED Station Inventory

Suggested minimum quantities of supplies:

1. One ForeRunner AED
2. One storage bracket or container (optional)
3. One installed battery and one spare
4. One carrying case (optional)
5. One razor (optional)
6. One set of gloves (optional)
7. One User's Guide
8. Two sets of electrodes
9. One installed PC data card and one spare (optional)
10. One mouth barrier device
11. One pair of scissors (optional)
12. 4x4 gauze (optional)

Location of AED Stations Example:

Station: 1 Device Serial #: 14986
Building: Manufacturing Building #2
Floor: Ground floor
Location on floor: First aid station (next to cafeteria).

Station: _____ Device Serial #: _____
Building: _____
Floor: _____
Location on floor: _____

APPENDIX E
MAINTENANCE GUIDELINES

I. Self Tests and ForeRunner Maintenance

The ForeRunner automatically performs periodic self test when a battery is installed and has enough power to perform the tests. The ForeRunner displays a message during these tests indicating that a self test is running.

If you press On/Off during a self test, you discontinue the test. The test is automatically rescheduled.

The results of the automatic self tests are displayed on the Status Indicator.

If the ForeRunner passed its last automatic self test, the Status Indicator alternates between dark square and hourglass shapes.

A self test error, storage of the ForeRunner outside of the recommended temperature range, or a low or partially depleted battery results in a flashing **X** displayed on the Status Indicator accompanied by a chirping sound. A solid **X** is displayed if a Training or Setup Card is installed, the battery is missing or fully depleted, or a self test failure occurs.

If the Status Indicator displays anything other than the alternating hourglass shapes, such as a constant dark shape or a flashing or solid **X**, remove the ForeRunner from service. If there is no "low battery" or "replace battery" screen message, remove and reinstall the existing battery and perform the Battery Insertion test (BIT) as described in the Quick Reference User's Guide, Chapter 2, *Putting the ForeRunner into Service*. If the BIT passes and the Status Indicator alternates dark and hourglass shapes, return the ForeRunner to service. If the BIT fails, install a new battery and repeat the BIT a second time. If the BIT passes, return the ForeRunner to service. If the BIT fails, remove the ForeRunner from service and contact Customer Service.

The ForeRunner is designed to be transported, stored, and operated within the environmental conditions specified in Appendix B of the Quick Reference User's Guide. ForeRunner performance may be decreased outside of these conditions.

Self Tests During Use:
The ForeRunner performs a Power On Self Test (POST) each time you turn it on. Self tests continue to monitor the hardware and software systems and battery while the ForeRunner is in use.

II. Maintenance Schedule

The following table provides suggested frequencies for maintenance. Different frequency intervals may be appropriate depending upon the environment in which the ForeRunner is used, and is at the discretion of the regional Medical Director.

Frequency	Observe	Take Action
Daily, and after each use	Check the Status Indicator. Verify that you see alternating dark and hourglass shapes that indicate the ForeRunner is ready to use.	If you see any condition other than the alternating dark square and hourglass shapes such as a constant dark shape, a flashing red **X** or a solid red **X**, do the following. If there is no "low battery" or "replace battery" screen message, remove and reinstall the existing battery and perform the BIT. If the BIT passes and the Status Indicator alternates dark and hourglass shapes, return the ForeRunner to service. If the BIT fails, install a new battery and repeat the BIT a second time. If the BIT passes, return the ForeRunner to service. If the BIT fails, remove the ForeRunner from service and contact Customer Service.
	Ensure that all supplies, accessories, and spares are present, undamaged, and have not passed their expiration dates.	Do not use damaged or expired supplies, accessories, or spares. Replace supplies, accessories, and spares as needed. Do not leave electrodes connected to the ForeRunner when not in use.
Weekly and after each use	Ensure the exterior of the ForeRunner and the connector socket are free of cracks and signs of damage.	Perform a BIT if the ForeRunner is damaged or subjected to abuse. If cracks or damage are noted, remove the ForeRunner from service and contact Heartstream Customer Service.

Frequency	Observe	Take Action
After each use	PC data card	Remove the used PC data card and replace it with a spare. Apply the patient ID label to the PC data card and deliver the card to appropriate personnel according to local guidelines and medical protocol.
	Ensure the ForeRunner exterior and connector socket are free of dirt or contamination Status Indicator	Clean the ForeRunner, if needed. Perform the BIT according to instructions.

Calibration is unnecessary as the ForeRunner automatically performs daily self tests and correct operation is verified during the BIT. The ForeRunner does not require manual verification of energy delivery because monthly automatic self tests verify the waveform delivery system.

The ForeRunner has no user serviceable parts and Heartstream is the sole repair facility for the unit. As a result, we do not publish Service/Maintenance and Repair Manuals for technical professionals.

> **CAUTION:** Improper maintenance can cause the ForeRunner not to function. Maintain the ForeRunner only as described in the User's Guide or as designated by your program's medical director.
>
> **CAUTION:** Electrical shock hazard. Dangerous high voltages and currents are present. Do not open unit, remove covers, or attempt repair. There are no user serviceable components in the ForeRunner. Refer servicing to qualified service personnel.

III. Cleaning

To clean the ForeRunner, observe the following guidelines:

- The ForeRunner should only be cleaned with the battery in place to keep fluids out of the PC data card slot and battery contact area.
- Use a soft cloth. Do not use abrasive materials, cleaners, or strong solvents such as acetone, or acetone based cleaners.
- Do not immerse the ForeRunner in fluids.
- Clean the ForeRunner and the connector socket with appropriate cleaning agents listed below. The connector socket includes a slot to allow thorough cleaning.

Use only the following cleaning agents:

- Isopropyl alcohol (70% solution)
- Soapy water
- Chlorine bleach (30 ml/l water)
- Ammonia based cleaners
- Glutaraldehyde based cleaners
- Hydrogen peroxide

CAUTION: Do not immerse any portion of the ForeRunner in water or other fluids. Do not allow fluids to enter the ForeRunner. Avoid spilling any fluids on the ForeRunner or accessories. Spilling fluids into the ForeRunner may damage it or present a fire or shock hazard. Do not autoclave or gas sterilize the ForeRunner or accessories.

The following checklist is provided for your reference.

Automated Defibrillators: Operator's Check List

ForeRunner Model No.: _____ Serial No.: _____

ForeRunner Location or vehicle ID: _____

Inspect the ForeRunner at frequencies specified or as designated by your medical director. Indicate whether all requirements have been met. Note any corrective action taken. Sign at the bottom of the form.

Date							
Frequency Interval							
ForeRunner Unit Clean, no dirt or contamination; no damage present							
Supplies Available: a. Two sets defibrillation pads, sealed, within expiration date, undamaged b. Ancillary supplies (Hand towel, scissors, razor) c. Spare unopened battery within "Install Before" date d. PC data card undamaged, with spares*							
Status Indicator a. Self test okay, verify by noting Status Indicator							
Inspected by:							
Remarks, Problems, Corrective Actions							

* Applicable only if unit uses this option.

APPENDIX F
DATABASE AED TRACKING

AED ORGANIZER

DATA MANAGER

AED

RESPONDER

TRAINER

FACILITY

APPENDIX G
AED and FAA
EQUIPMENT COMPATIBILITY

ELECTROMAGNETIC COMPATIBILITY TEST REPORT OF RADIATED EMISSIONS FROM THE SEMI-AUTOMATIC EXTERNAL DEFIBRILLATOR

FINAL (Revision 1)

August, 2000

Prepared By:
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1. PURPOSE

The purpose of this activity was to investigate the radiated emissions from the Semi-Automatic External Defibrillator (AED) manufactured by Heartstream. Of particular interest, are the radiated emissions that occur in the 30-1230 MHz and 1560-1580 MHz portions of the frequency bands used by Civil Aviation. Radiated emissions from the Semi-Automatic Defibrillator are compared to the radiated emissions criteria in *RTCA DO-160D, Category M, Environmental Condition And Test Procedure For Airborne Equipment, Section 21, Emission Of Radio Frequency Energy Cat. A & Z.*

2. BACKGROUND

The Office of Spectrum Policy and Management (ASR) tasked the FAA William J. Hughes Technical Center's Spectrum Engineering Section (ACT-330) to perform tests to ascertain the AED emissions characteristics. Because the AED will be used on aircraft and in FAA facilities, they have the potential to generate radio frequency interference (RFI) that may fall in Civil Aviation frequency bands. RFI could cause erroneous readings on aircraft navigation systems or interfere with Air Traffic Control voice communications.

3. DESCRIPTION

This AED is the Heartstream ForeRunner Semi-Automatic External Defibrillator, Serial Number 03264. It is a portable, battery operated, semi-automatic defibrillator. The unit operates on a disposable 18 VDC Lithium battery and weights about 5.8 lbs. with battery.

4. TEST APPROACH

In order to record radiated emissions data from the AED, it was decided to test it inside a shielded room located inside the Hangar Building at the FAA Technical Center. The shielded room reduces signals from the environment to acceptable levels. Figure 1 shows the test setup.

The AED was mounted on a tripod and raised to a one-meter height. A receive antenna was placed at a one meter height and one meter from the AED to capture any emission radiated by the AED.

The receive antenna cable was connected to a spectrum analyzer located outside the shielded room. A laptop computer used HP VEE (Hewlett-Packard Visual Engineering Environment) software to control and record data from the spectrum analyzer. Data was collected from 30-310 MHz (Biconical, Folding see description next page), from 310-1230 MHz and 1560-1580 MHz (Log Periodic see description next page) with the receive antenna oriented horizontally.

A portion of data was also collected outside of building 176 (Experimental RCAG); the test setup is as same as inside Shielded room, except it is outside of building 176.

The test equipment and antennas used for this effort are listed below:

- 1 Hewlett Packard spectrum analyzer model HP 8568B. Calibration due 10/2000.
- 1 Laptop Computer Toshiba Pentium I using HP-VEE (Hewlett-Packard Engineering Environment) software to collect data.
- 1 Biconical, Folding Antenna, manufactured by A.H Systems Inc. Model SAS-200/530,542, frequency range 20- 330 MHz. Dimensions: 29"H x 52"W and 4.3 lb.'s in weight. Calibration due 2/01.
- 1 Log-Periodic Antenna manufactured by A.H Systems Inc. Model SAS-200/510, frequency range 290-2000 MHz. Dimensions: 22"H x 20"W and 2.5 lb.'s in weight. Calibration due 2/01.
- 1 HP signal generator model HP8657. Calibration due 10/2000.
- 1 Forerunner Semi-Automatic External Defibrillator (AED) manufactured by Heartstream, serial # 03264.
- RG-214 cables.
- 1 Shielded room 12'x12'x12'

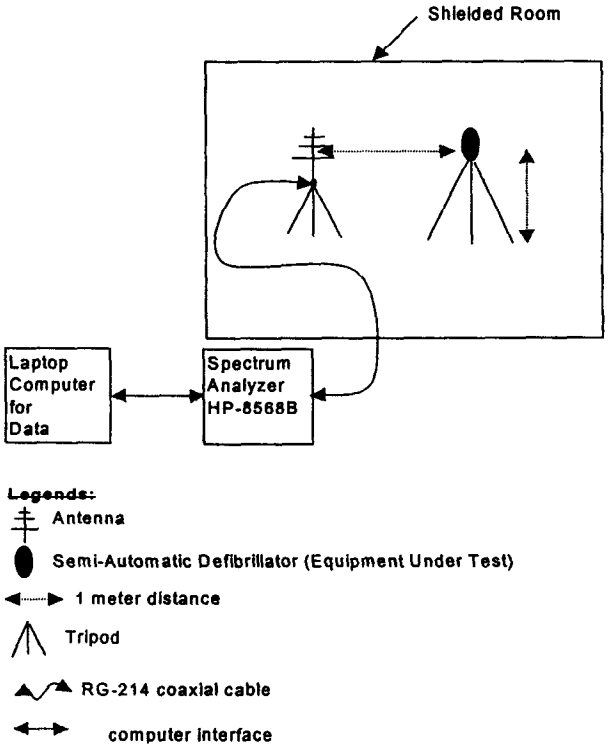

Figure 1. Defibrillator Test Setup

5. DATA COLLECTION

Radiated emissions data was collected for one Forerunner AED. These tests were performed using a computer to control and set the spectrum analyzer for each frequency range and to record the amplitude of the radiated emissions. To capture the low level signals emitted by the AED, the resolution and video bandwidths of the spectrum analyzer were set to 10 kHz, the reference level was set to -40 dBm, attenuation 0 dB, and the sweep time was 600 milliseconds.

Due to the signal reflection inside the shielded room, a portion of the data was recollected outside of building 176. Frequency ranges recollected outside of building 176 were 110-150 MHz and 275-280 MHz. See **6.2 Plot # 2** for more details.

6. DATA ANALYSIS

To compare this data to the requirements of RTCA-DO-160D, the spectrum analyzer signal level measured in dBm was converted to field strength in dBuV per meter (dBuV is decibels referenced to 1 micro volt).

6.1 Plot #1

See the attachments for, Plot # 1 (frequency range from 30-600 MHz) and Plot # 1 continued (frequency range from 600-1230 MHz and 1560-1580 MHz). Because the Excel file is out of data range, two plots are needed for Plot # 1.

On Plot #1, the yellow line is the criteria from RTCA-DO-160D, the green line is FCC Part 15, the dark blue line is baseline, the pink line is Defibrillator turned on in charging mode, and the light blue line is AED turned on in monitoring mode.

The light blue line, which is the AED turned on in its monitoring mode, shows a signal level at 129.12 MHz and 133.08 MHz exceeding the RTCA-DO-160D limit line by about 5 dB and 2 dB, respectively. Both these frequencies are within the 118 to 137 MHz band used for aircraft communications). At 108.96 MHz, which is within the 108 to 118 MHz band used by ILS, VOR, and SCAT-1, the criteria was exceeded by 1.5 dB. At 145.24 MHz the criteria was exceeded by 2 dB.

The pink line shows the AED turned on in charging mode which is the worst case. It shows signal levels at 133.08 MHz exceeding RTCA-DO-160D limit line by about 8 dB at 134.84 MHz by 2 dB, and at 278.28 MHz by 1.5 dB. These three frequencies are within aircraft communications bands. At 141.2 MHz the criteria was exceeded by 3 dB and at 145.24 MHz by 2 dB.

All the above signal levels from plot # 1, which exceeded the RTCA-DO-160D limit line are due to reflections from the Shielded room walls. They are not actual radiated emission levels from the AED. To prove that the above out of tolerance signals were due to reflections, additional data was collected outside Building 176 in the 110 to 150 MHz band and in the 275 to 280 MHz band. This data is presented on Plot # 2. Since the rest of Plot # 1 data shows that the RTCA-DO-160D limit was not exceeded, there is no need to recollect data for the rest Plot #1.

6.2 Plot # 2

Plot # 2 contains a small portion of data, covering the frequency ranges from 110-150 MHz and from 275-280 MHz. This data was recollected outside because it exceeded the RTCA-DO-160D criteria due to the reflections inside the shielded room.

The yellow line is criteria from RTCA-DO-160D, the green line is FCC Part 15, the dark blue line is baseline, and the pink line is AED turned on in charging mode.

The dark blue line exceeds the yellow line by a few dB. However, *it is baseline data or environmental noise (with the AED turned off)*, not radiation from the AED.

The pink line shows the radiation from the AED does *not exceed* the yellow line.

Plot # 2 shows no radiated emissions from the AED that exceeded the RTCA-DO-160D criteria in frequency ranges from 110-150 MHz and from 275-280 MHz. This proves the Plot # 1 data that exceeded the criteria was due to reflections.

Because charging mode is the worst case, Plot # 2 has only data in charging mode.

7. CONCLUSION

The AED has more radiated emission levels during charging mode than during monitoring mode.

Plot # 1 shows some signal levels exceeding the RTCA-DO-160D limit line, but those signal levels are due to the reflections in the shielded room; *it is not real radiation from the AED*. Therefore, a portion of Plot # 1 was recollected for the 110-150 MHz and 275-280 MHz bands. This data, which is shown in Plot # 2, *shows no radiated emission from the AED unit that exceeds the RTCA-160D limit line.*

Since this data is based on tests performed on only one AED unit, it is impossible to predict if other AED units may have stronger emissions in civil aviation bands. Therefore, AED units used in a certain aircraft or environmental applications may need to be tested.

APPENDIX H
FAA AED INCIDENT REVIEW

Patient Name:_____

Facility:_____Phone:_____

Location:_____

TIMES:

Cardiac arrest for this event recognized: Date _____ Time: _____AM/PM

First response at: Time: _____AM/PM 911 Called: _____AM/PM

CPR Initiated: _____AM/PM

AED 1st Shock at: _____AM/PM Effective: Yes ____ No ____

AED 2nd Shock at: _____AM/PM Effective: Yes ____ No ____

AED 3rd Shock at: _____AM/PM Effective: Yes ____ No ____

AED 4th Shock at: _____AM/PM Effective: Yes ____ No ____

AED 5th Shock at: _____AM/PM Effective: Yes ____ No ____

EMS on scene at: _____AM/PM

Patient condition at time of EMS departure: CPR in Progress ☐ Awake and Alert ☐
Other: _____

FAA Responders: 1._____ 2:_____
3:_____ 4:_____
Transported to: _____

Comments (please describe any problems encountered): _____
_____
_____

MEDICAL CONTROL (REGIONAL MEDICAL DIRECTOR use only)

Final Patient Disposition _____
Comments:_____
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